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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,617	03/25/2004	Katy Drieu	427.035-DIV.	7475

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HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	**PAPER NUMBER**
1657	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,617	DRIEU, KATY	
	Examiner	Art Unit	
	Tiffany M. Gough	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 10-16* is/are pending in the application.

4a) Of the above claim(s) *7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09555906.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

As discussed today,11/7/2006, with applicants representative Mr. Charles Muserlian, in view of the restriction requirement by the previous examiner and applicants response, claims 4,5,10-16 have been re-grouped and elected without traverse.

Claims 1-3,9 have been cancelled by applicant in the amendment filed 9/05/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 and it's dependents are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alleviating withdrawal symptoms associated with alcohol, amphetamine and morphine withdrawal, does not reasonably provide enablement for tobacco dependency withdrawal symptoms and/or **any withdrawal symptom associated with any substance dependency or addiction**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to alleviate any and all withdrawal symptoms associated with any and all substance dependencies or addiction. One of skill in the art would not expect to practice the invention commensurate in scope with these claims.

The claims therefore encompass alleviating any and all withdrawal symptoms for any and all substance dependency or addiction of pressures, for which no written description has been provided. However, the sole examples provided in the disclosure of alleviating withdrawal symptoms associated with alcohol, amphetamine and morphine withdrawal are supported by applicants disclosure. Given the property differences among the many different drugs/substances/chemicals which humans develop addiction to and the different symptoms associated with each drug, one of ordinary skill in the art would not expect to be able to use the disclosed Ginko biloba extract to alleviate any or all withdrawal symptoms in a human suffering from any substance dependency or addiction as encompassed by the current claim language. Thus, with the exception of the above stated drugs, and in view of the lack of any specific guidance with respect to the symptoms associated with specific drugs other than what is encompassed by the claims, one skilled in the art would expect a trial and error process to determine whether or not the extract encompassed by the claims would apply to the as disclosed application, and would further have to determine through undue experimentation, without guidance from the specification, how to alleviate the withdrawal symptoms associated with each specific drug/chemical/substance.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to decide if the Ginko biloba extract would alleviate withdrawal symptoms associated with any substance dependency or addiction, limited amount of guidance and limited number of working examples in the specification to determine whether tobacco and all other substances causing

dependency and withdrawal along with the symptoms of each could be alleviated ; nature of the invention; state of the prior art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and it dependents are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, applicant fails to distinctly claim the symptoms and drug/substance they are associated with, which are being alleviated by the Ginkgo biloba extract. Thus, it is confusing as to what drug and associated symptoms are being alleviated by the extract.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4,5,10-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2 and 7 of U.S. Patent No. 6936285. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 is generic to all that is recited in claim 1 of U.S. Patent No.

6936285. That is, claim 1 of U.S. Patent No. 6936285 falls entirely within the scope of claim 11 or, in other words, claim 11 is anticipated by claim 1 of U.S. Patent No. 6936285. Specifically, withdrawal symptoms associated with alcohol, amphetamine and morphine withdrawal anticipates withdrawal symptoms associated with any substance dependency or addiction or drugs, which induce toxicomania. Thus, a patent to the genus would therefore extend the rights of the species should the genus in the application under examination be issued as a patent after the species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4,5,10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia et al (US 5976548) or Kleijnen (Lancet, vol 340,1992) or Blumenthal (The complete german Commission E Monographs,1998) supported by O'Reilly(EP 0436129 A) in view of McChargue et al (Experimental and Clinical Psychopharmacology, vol. 6, 1998) and http://www.netdoctor.co.uk/smoking/withdrawalsymptoms_000507.htm

Applicant claims a method of alleviating withdrawal symptoms in a human for substance dependency or addiction by administering an amount of ginkgo biloba extract

sufficient to alleviate the withdrawal symptoms. Applicant further claims the extract to be either form a ginkgolide (either A or B), a pharmaceutical salt thereof, a glycosylated ginkgolide, an alkolated ginkgolide and an acylated ginkgolide. Further, the extract is said to comprise 3.5 to 1% of ginkgo biloba A,B,C and J, 40-60% of flavoneglycosides, and 5-7% of bilobalide wherein the ginkgo biloba extract contains at least 5% at atleast 50% of ginkgolides. The substance can be any drug inducing toxicomania or tobacco.

Hsia teach a composition comprising ginkgo biloba extract , including ginkgolide B which enhance memory; absent mindedness, confusion, headaches, and the ability to concentrate, improving cerebral metabolism, cerebral dysfunction, circulatory disturbances (see columns 2, lines 35-55, col. 4, lines 34-40).

Kleijnen teach ginkgo to be used therapeutically for cerebral insufficiencies, such as difficulty concentrating, memory, absent mindedness, confusion, lack of energy, tiredness, decreased physical performance, depression, anxiety, dizziness, tinnitus and headaches. They disclose ginkgo extracts to contain flavonoids, i.e. flavoneglycosides, ginkgolides (A,B,C and J) and bilobalide (see p. 1136 3rd, 4th parapraphs).

Blumenthal teach a ginkgo biloba extract containing 22-27% flavone glycosides, 2.8-3.4% ginkogolides A,B,C , 2.6-3.2% bilobalide and <%ppm ginkgolic acids which is used to increase memory performance, compensate for a disturbed equilibrium, improve blood flow and hypoxic tolerance, treat memory deficits, disturbances in concentration, depression, dizziness, tinnitus and headaches.

O'Reilly disclose a therapeutic Ginkgo biloba extract composition containing 40-60% flavone glycosides, 5.5-8% ginkgolides (A,B,C and J) 5-7% bilobalide and a maximum of 10 ppm alkylphenol compounds.

Neither Hsia, Kleijnen, or Blumenthal teach a method of alleviating withdrawal symptoms specifically associated with substance dependency or addiction.

However, Remington's Pharmaceutical Sciences teach withdrawal symptoms from alcohol, cigarettes, amphetamines, marijuana etc. to be central nervous system disturbances, loss of memory, impairment in hearing, headaches, disorientation, agitation, reduced oxygen transport, tinnitus (see p. 1290-1296).

McChargue teach tobacco/nicotine withdrawal symptoms to be irritability, anxiety, difficulty concentrating, restlessness and insomnia.

http://www.netdoctor.co.uk/smoking/withdrawalsymptoms_000507.htm disclose nicotine/tobacco withdrawal symptoms as irritation, anger, headaches, difficulty concentrating, depression, fatigue, dizziness, anxiety.

Thus, as disclosed above, withdrawal symptoms associated with substance dependency and addiction are known. These symptoms are also disclosed in the art as being alleviated by ginkgo biloba extracts.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use ginkgo biloba extracts to alleviate symptoms associated with substance dependency and /or addiction because ginkgo biloba extracts are disclosed in the art as being used to alleviate symptoms such as headaches, difficulty concentrating, anxiety, central nervous system disturbance's, tinnitus , loss of memory,

depression etc. , all of which are known symptoms associated with substance abuse and addiction.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to use ginkgo biloba extracts with a reasonable expectation for successfully alleviating withdrawal symptoms associated with substance dependency and/or addiction because, while withdrawal symptoms associated with substance dependency and/or addiction are known in the art, ginkgo is also known to be used therapeutically to relieve such symptoms.

While neither reference teach the exact concentrations of the extract, it would be obvious to optimize these result effective variables by routine experimentation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the

motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05

Thus, the invention as a whole is prima facie obvious over the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tiffany Gough

RUTH DAVIS
PRIMARY EXAMINER